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Food and Agricultural Import Regulations and Standards

European Union Report

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Report Highlights:
This report gives an overview of food laws currently in force in the EU-25. The following sections were updated: food laws, labeling (allergen labeling and health claims), packaging waste management, pesticides and contaminants, certification and inspection, GMOs, wine, geographical indications, EU initiatives.

Includes PSD Changes: No
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DISCLAIMER: This report was prepared by the Office of Agricultural Affairs, U.S. Mission to the European Union in Brussels, Belgium for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

SECTION 1. FOOD LAWS

The European Union (EU), formerly known as the European Economic Community (EEC), was created by the Treaty of Rome on March 25, 1957. Through several accessions, the EU has gradually expanded to become the world's largest multi-nation trading bloc. Since May 1, 2004, the European Union comprises 25 member states with over 450 million consumers. Bulgaria and Romania are set to join the EU in 2007, which will further raise the EU population by 30 million people.

EU member states: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom.

All EU Member countries accept the entire body of EU laws and obligations associated with the treaties and agreements to which the EU is a party, including the EU laws and rules pertaining to processed foods.

Originally created as a customs union, the process of harmonizing existing Member State legislation has been long and cumbersome and is still ongoing. While the vast majority of food laws and regulations have been harmonized throughout the EU, the single EU market is still not a *fait accompli.* It is important to note that when EU-wide legislation is incomplete or absent, the laws of Member States apply, often resulting in different rules in different Member States. The FAIRS reports prepared by the Offices of Agricultural Affairs in the EU Member States are excellent sources of information on Member State specific requirements (http://useu.usmission.gov/agri/fairs.html).

The main principle of the single market concept is to ensure that all food products, whether produced in the EU or imported from a third country, can move freely throughout the EU if they comply with the requirements. In reality, certain directives allow Member States to make exceptions e.g. in cases where a country can prove health concerns about a product intended for import. Free movement can only be guaranteed when all aspects are covered by harmonized legislation: e.g. a foodstuff may comply with the labeling directive but may carry a health claim for which harmonized rules do not yet exist.

Imported products must meet existing Member State requirements in cases where EU regulatory harmonization is not yet complete.

EU legislation is made up of Directives and Regulations. These are all translated into the twenty official languages in use in the EU-25. Translations into the new EU languages of legislation in force in the EU-15 prior to accession in May 2004 of the 10 new Member States are available from the EU website (http://eur-lex.europa.eu/en/enlargement/enlargement.htm). **Directives** define the result that must be achieved but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption). **Regulations** are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments to EU legislation are usually published in new and separate Directives and Regulations, making it difficult to be sure of all possible amendments when doing research. When legislation is referenced in this guide, it is implied that all further amendments also apply.

The EU has followed a dual approach in harmonizing food laws: "horizontal" legislation that covers aspects which are common to all foodstuffs (such as additives, labeling, hygiene, etc.) and "vertical" legislation on specific products (e.g., cocoa and chocolate products, sugars, honey, fruit juices, fruit jams, novel foods, etc.).

In the aftermath of the BSE crisis and several other food scandals in the late 1990s, the EU published in Jan 2000 its White Paper on Food Safety setting out a legislative action plan for a pro-active new food policy. The EU developed a "Farm to Fork" approach covering all sectors of the food and feed chain, with traceability as basic concept. The application of the "precautionary principle" as described in the February 2000 Commission Communication on the Precautionary Principle is also an important concept in the EU's approach. Key elements in the new approach were the establishment of a framework laying down the general principles and requirements of EU food law, the establishment of an independent body providing scientific advise to the legislators (EFSA), the development of specific food and feed safety legislation including a major overhaul of the existing hygiene legislation, and the creation of a framework for harmonized food controls. The new regulations on general food law, food and feed controls, food hygiene and feed hygiene are the framework regulations for the new EU food safety system. Revisions of existing EU food regulations or new regulations all implement the principles contained in the new framework regulations.
Information on the EU's food safety approach is available on our website at http://useu.usmission.gov/agri/foodsafe.html.

EU political structures include the permanent bureaucracy of the Commission, the Council of Member State representatives, and the European Parliament. All are involved in creating and passing legislation. For more information on how the EU works, see the website of the European Commission at http://europa.eu.int/index-en.htm. It is the task of the European Food Safety Agency (http://www.efsa.eu.int) established together with the general food law, to provide scientific advice to the legislators on matters related to food safety.

Enforcement of EU food legislation is done by Member State officials. Auditing oversight of Member State performance is done by EU Commission officials. The EU Commission has the power to initiate legal action in the European Court of Justice against Member States who are not complying with EU Directives and Regulations.

Exporters should be aware that there is possibly some variation among Member States in applying EU harmonized legislation. This may result from the lack of harmonized guidelines for the enforcement of rules; it may be due to variations in the transitional period needed to adjust to EU rules; there may be temporary waivers or exemptions –usually called derogations; in certain cases there may be room for interpretation of EU harmonized legislation; certain aspects which are not regulated in detail at EU level may be handled differently in different Member States, e.g. acceptability of stick-on labels varies among Member States. Also, there is a wide variation in inspection fees, in registration fees and in the time required to evaluate dossiers on products used in the course of the food production process.

Up to date information on EU food import rules as well as general information on EU import duties and quotas can be found on our website at http://useu.usmission.gov/agri/usda.html. The website also links to additional sources of useful information.

AS A REMINDER: Imports of red meat, meat products, farm and wild game meat, ratites, milk and milk products, seafood, bovine embryos an semen, porcine and equine semen, gelatin and animal casings to the EU from the U.S. may only originate from EU approved U.S. establishments (see section 9.A for more details).

SECTION 2. LABELING REQUIREMENTS

http://useu.usmission.gov/agri/label.html

A. General Requirements

The standard U.S. label fails to comply with EU labeling requirements.

General provisions on the labeling, presentation and advertising of foodstuffs marketed in the EU are laid down in European Parliament and Council Directive 2000/13/EC. It applies not only to foodstuffs intended for sale to the ultimate consumer but also for supply to restaurants, hospitals and other mass caterers. Section 7 covers labeling requirements for specific products, including genetically modified and novel foods.

Compulsory Information:

- The name under which the product is sold.

- The list of ingredients, in descending order of weight. Important exceptions include added water in foods reconstituted from concentrates, and cheese, which is covered by special rules. The following ingredients require a specific statement on the label: GMO's, packaging gases, sweeteners, aspartame and polyols, quinine and caffeine, phytosterols and phyostanols and licorice.

New food allergen labeling rules were introduced by Directive 2003/89/EC and entered into force on November 25, 2005. Under this directive, the following 12 groups of potential allergenic ingredients must be indicated on food labels: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk and dairy products (including lactose), nuts and nut products, sesame seeds and sulphite at concentrations of at least 10 mg per kg or 10 mg/l, celery, and mustard. Allergen labeling also applies to alcoholic beverages. GAIN report E36066 lists the different languages that the EU member states will accept for the purpose of allergen labeling of wine. Guidelines for the implementation of the new allergen labeling rules are available on the Commission's website at http://europa.eu.int/comm/food/food/labellingnutrition/foodlabelling/guidelines_6_10.pdf. These guidelines also specify in which cases derogations may be accepted: for foodstuffs for which no ingredients list is required, for sub ingredients of certain compound ingredients, for ingredients which belong to well defined categories and for substances that are not regarded as ingredients. Directive 2005/26/EC establishes a list of allergen derivatives that, based on the European Food Safety Authority's risk assessments, are temporarily exempted (until November 25, 2007) from mandatory labeling. For more information on the implementation of the allergen labeling rules see GAIN report E35196.

- Certain ingredients may be designated by the name of the category rather than the specific name (Annex I to Directive 2000/13/EC). These include fats, oils (note that peanut oil is also subject to the new allergen rules), starch, fish, cheese, spices, herbs, gum bases, crumbs, sugar, dextrose, glucose syrup, milk proteins, cocoa butter, crystallized fruit, vegetables and wine. Directive 2001/101/EC adds meat as a category and defines the term "meat" for the labeling of pre-packed meat-based products (for more information see GAIN report E23004).

- The quantity of certain ingredients or categories of ingredients (QUID) – see below.

- The net quantity of prepackaged foodstuffs expressed in metric units (liter, centiliter, milliliter, kilogram or gram).

- The date of minimum durability: the shelf life is indicated by the words "Best before..." when the date includes an indication of the day, or by "Best before end of..." in other cases. The date has to be given in order of day- month-year. However, for foodstuffs with a shelf life of less than three months, the day and month of expiry are adequate; for a shelf life of three to eighteen months the month and year are sufficient; for more than eighteen months shelf life the year is sufficient indication. In the case of highly perishable foodstuffs the date consisting of the day, the month and possibly the year has to be preceded by the words "use by."

- Any special storage conditions or conditions of use.

- The name or business name and address of the manufacturer, packager or vendor established within the Community.

- Particulars of the place of origin or provenance in case absence of such information might mislead the consumer.

- Instructions for use.

- The actual alcoholic strength for beverages containing more than 1.2 percent alcohol by volume.

- A mark to identify the lot to which a foodstuff belongs, determined by the producer, manufacturer or packager or by the first seller in the EU. The marking must be preceded by the letter "L", except in cases when it is clearly distinguishable from other indications on the label. The lot identification is not necessary if the date (day and month) of minimum durability or "use by" date, appears in un-coded form on the label.

- Treatments undergone, with specific indications for irradiated foods and deep-frozen foods (see section 7).

Note: the use of the EAN (European Article Numbering) product coding system is not regulated by EU law. However, this bar code system is commonly used in the EU to fulfill the traceability requirement, which became mandatory on January 1, 2005 (See also GAIN 35112).

Additives

- Annex II to the labeling directive lists the categories of additives, which must be designated by the name of their category followed by their specific name or EEC number. The categories are the following: color, preservative, anti-oxidant, emulsifier, thickener, gelling agent, stabilizer, flavor enhancer, acid, acidity regulator, anti-caking agent, modified starch, sweetener, raising agent, anti-foaming agent, glazing agent, emulsifying salts, flour treatment agent, firming agent, humectant, bulking agent, propellant gas.

- Flavorings: Annex III to the labeling directive describes the way of designating flavorings in the list of ingredients.

- The presence of sweeteners/aspartame/polyols requires standardized statements on the label; packaging gases are not considered as additive but also require a standardized statement.

Quinine and Caffeine

Commission Directive 2002/67/EC requires the compulsory labeling of quinine and caffeine used in the production or preparation of foodstuffs (usually tonic waters and energy drinks). Quinine and caffeine must be mentioned in the ingredients list, preceded by the term "flavoring". Beverages containing more than 150 mg of caffeine per liter will have to be labeled with "high caffeine content" followed by the caffeine content expressed in mg/100 ml.

Licorice

Commission Directive 2004/77/EC, scheduled to come into force on May 20, 2005, lays down rules for the labeling of confectionery and beverages containing glycyrrhizinic acid and its ammonium salt (licorice).

Phytosterols & Phytostanols

Commission Regulation 608/2004 lays down labeling requirements for foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and phytostanol esters (used to reduce cholesterol levels). For labeling purposes, they must be designated respectively by the terms “plant sterols”, “plant sterol esters”, “plant stanols” and “plant stanol esters”.

Quantitative Ingredients Declaration (QUID)

Quantitative ingredients declaration (QUID) is compulsory in the following cases:

- Where the ingredient or category of ingredients appears in the name under which the foodstuff is sold:
e.g. "15% strawberries" on strawberry ice cream - QUID for strawberries
"35% fruit" on fruit pie - QUID for total fruit content

- Where the ingredient or category of ingredients is usually associated with that name by the consumer: e.g. goulash soup - QUID for beef

- Where the ingredient or category of ingredients is emphasized on the labeling in words (e.g. "made with butter"), pictures (e.g. of a cow to emphasize dairy ingredients) or graphics (different size, color and/or style of print).

- Where the ingredient or category of ingredients is essential to characterize a foodstuff and to distinguish it from similar products.

The QUID declaration must be indicated in or immediately next to the name under which the product is sold, unless a list of ingredients is voluntarily indicated on the label in which case the quantity may appear in the list. The quantity of the ingredient, expressed as a percentage, must correspond to the quantity of the ingredient(s) actually used in the preparation of the product.

The QUID requirement DOES NOT apply to constituents naturally present in foods and which have not been added as ingredients e.g. caffeine (in coffee) and vitamins and minerals (in fruit juices). QUID declarations are not needed in a number of cases, e.g. when products state the drained net weight or where an ingredient is used for purposes of flavoring. QUID declarations CANNOT replace nutrition labeling.

Commission Directive 1999/10/EC provides for exemptions from the QUID requirement:

- When the wording "with sweeteners" or "with sugar(s) and sweetener(s) accompanies the name under which a foodstuff is sold.
- When the addition of vitamins and minerals is subject to nutrition labeling.
- When foodstuffs are concentrated or dehydrated.

General guidelines have been drawn up to help Member States and industry organizations implement the principle of QUID. A copy of these guidelines are available on our website at http://useu.usmission.gov/agri/label.html.

Language Requirements

As a general rule, labeling has to be in a language easily understood by consumers; this is in practice the official language(s) of the member state. As an exception to the general rule, it is also allowed to use:

- Another language provided it can easily be understood by consumers.
- Other means depicting the content (e.g. pictures).

Multi-language labeling is allowed throughout the EU.

Language labeling requirements in practice:

EU Member State	Language
Austria	
Belgium	French AND Dutch, German also recommended
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	British English
Italy	Italian
Latvia	Latvian
Lithuania	Lithuanian
Luxembourg	French or German
Malta	Maltese or English or Italian
Netherlands	Dutch
Poland	Polish
Portugal	Portuguese
Slovakia	Slovak
Slovenia	Slovene
Spain	Spanish
Sweden	Swedish
United Kingdom	British English

Stick-on Labels

EU legislation does not contain any reference to the use of stick-on labels. It is up to individual Member States whether to accept stick-on labels.

Samples

EU legislation covers all foods destined for consumption. It does not contain any specific labeling requirements or exceptions for samples. Exporters are advised to consult the member state FAIRS reports for specific information (http://useu.usmission.gov/agri/fairs.html).

Labeling of Genetically Modified Foods and Novel Foods

Section 7.A of this report is entirely dedicated to the regulatory review and commercialization of genetically modified foods in the EU and provides information on EU labeling requirements for genetically modified foods and their derivatives. The words "produced from genetically modified ..." or "genetically modified" as a footnote or specification following the ingredient have to be used to indicate the presence of the GM soy and corn proteins and all GM additives and flavorings that are currently on the market.

B. Medical / Health Claims

Medical claims, attributing to a foodstuff the property of preventing, treating or curing human diseases, are explicitly prohibited in the EU general labeling directive. The directive does not provide any guidance on which health claims (e.g."Aids Digestion") are allowed and which not. As a result, many EU Member States have developed separate initiatives in this area. However, the EU has proposed new rules on health claims made on foods and adoption is expected in September/October 2006. For more information on the proposed EU rules on health claims see GAIN report E36086.

Requirements Specific to Nutritional Labeling

Nutrition labeling is not mandatory in the EU unless a nutrition claim is made on the label or in advertising messages. "Nutrition labeling" means any information on the label that relates to energy value and to the following nutrients: protein, carbohydrate, fat, fibre, sodium, vitamins and minerals present in significant amounts. A "nutrition claim" means any representation or advertising that claims that a foodstuff has particular nutritional properties and is only allowed if it relates to the energy value and/or nutrients referred to above. Nutrition labeling rules are laid down in Council Directive 90/496/EEC. A new regulation on the use of nutrition claims has been proposed by the Commission and adoption is expected in September/October 2006. For more information on the proposed EU rules on nutrition claims see GAIN report E36086.

Where nutritional labeling is provided, the information to be given should consist of either group 1 or group 2 in the following order:

Group 1	Group 2
- the energy value	- the energy value
- the amount of protein, carbohydrate and fat	- the amount of protein, carbohydrate, sugar, fat, saturates, fibre and sodium

The energy value and the proportion of nutrients must be declared in specific units per 100 grams or per 100 milliliters. Information on vitamins and minerals must be expressed as a percentage of the recommended daily allowance (RDA).

The information on the label must be presented in tabular form with the numbers aligned or if space does not permit, in linear form in a language easily understood by the purchaser.

C. Product-Specific Labeling

For a number of products, specific labeling requirements have been established in addition to the general requirements described above. These include:

- genetically modified foods
- novel foods
- foodstuffs for particular nutritional uses including dietetic and baby/infant foods
- beef
- wine
- spirit drinks
- organic foods
- cocoa and chocolate products, sugars, honey, fruit juices and similar products, preserved milk
- coffee extracts and chicory extracts, fruit jam, jellies, marmalades and chestnut puree
- fresh fruits and vegetables
- meat, eggs, dairy products, spreadable fats
- seafood

More details on above products can be found in Section 7.

SECTION 3. PACKAGING AND CONTAINER REQUIREMENTS

http://useu.usmission.gov/agri/packaging.html

A. Container Contents

Unlike the other requirements covered by this guide, requirements in the Directives concerning container contents of pre-packaged products set out below are not a prerequisite for marketing a foodstuff. However, if these requirements are satisfied, free movement throughout the EU is guaranteed.

The maximum tolerable error between the actual content and the quantity indicated on the label, and methods to check this are fixed in Council Directive 76/211/EEC, as amended. A small "e" of at least 3 mm on the label guarantees that the actual content corresponds to the quantity indicated. The size of the figures indicating the quantity depends on the nominal quantity:

- nominal quantity greater than 1000 g or 100 cl: at least 6 mm high
- greater than 200 g/20 cl but less than 1000 g/100 cl: at least 4 mm
- greater than 50 g/5 cl but less than 200 g/20 cl: at least 3 mm
- less than 50 g/2 cl: 2 mm. The quantity must be followed by the unit of measurement.

Container sizes have been prescribed for butter, fresh cheeses, salt, sugar, breakfast cereals, pasta, rice, dried fruits and vegetables, coffee, frozen fruits and vegetables, fish fillets, fish fingers, ice cream, preserved fruits and vegetables and products sold in metal containers. (Council Directive 80/232/EEC)

B. Packaging Waste Management

Member States are required to take measures to reduce packaging waste and must introduce systems for reuse, recovery and recycling of packaging materials (Council Directive 94/62/EC). To facilitate collection, reuse and recovery including recycling, an identification system for packaging has been drawn up (Commission Decision 97/129/EC). Its use is voluntary. A well-known and widely used recycling program is the German “green dot” system. More information can be found on the Packaging Recovery Organization Europe website which provides easy access to all Green Dot systems in Europe (www.pro-e.org).

C. Materials in Contact with Foodstuffs

European Parliament and Council Regulation 1935/2004 specifies the main requirements for materials that come into contact with foodstuffs, including active and intelligent packaging. This regulation entered into force on November 16, 2004 (except for the provisions on traceability which will apply from October 27, 2006) and repeals and replaces Directives 80/590/EEC and 89/109/EEC. It also sets out labeling & traceability requirements and the procedure for the authorization of substances through the European Food Safety Authority. Additional requirements will be proposed in specific measures and will include positive lists of authorized substances and/or materials. Annex I to regulation 1935/2004 lists the group of materials for which specific measures may be adopted. To date, specific directives have been developed for plastics, regenerated cellulose film, ceramics. In the case of ceramics, migration limits have been established for two of their constituents, namely lead and cadmium. Materials must bear an indication "for food contact" or the symbol reproduced in Annex II to Regulation 1935/2004.

Exporters are advised to verify if a Member State follows EU provisions as Member States are allowed to authorize provisionally the use of certain substances not listed in one of the specific directives. They may also restrict or temporarily prohibit the use of certain materials authorized by the specific directives for reasons of public health.

SECTION 4. FOOD ADDITIVE REGULATIONS
http://useu.usmission.gov/agri/additive.html

Council Directive 89/107/EEC provides for the establishment of EU harmonized positive lists --lists of what is permitted-- of a wide range of food additives. All food additives not included in the positive lists are prohibited except for those new food additives that receive a temporary two-year authorization by Member States. Most food additives may be used only in limited quantities in certain foodstuffs. Food additives for which no quantitative limits have been established (maximum level established at "quantum satis") must be used according to good manufacturing practice. This means using only as much as necessary to achieve the desired technological effect. Processing aids and flavorings fall outside of the scope of this directive.

Substances added to foodstuffs as nutrients such as minerals, trace elements, vitamins do not fall under the scope of this directive and continue to be subject to Member States legislation.

The lists of authorized food additives and their conditions for use are published in three directives:

1) European Parliament and Council Directive 94/35/EC on **sweeteners** for use in foodstuffs. The annex to this directive lists maximum usable doses for sweeteners in selected foodstuffs.

2) European Parliament and Council Directive 94/36/EC on **colors** for use in foodstuffs.
Annex I: list of permitted food colors. Only substances listed in this annex may be used
Annex II: foodstuffs which may not contain added colors
Annex III: foodstuffs to which only certain permitted colors may be added
Annex IV: colors permitted for certain uses only
Annex V: colors permitted in general and the conditions of use therefore.

3) European Parliament and Council Directive 95/2/EC, as amended, the so-called **miscellaneous additives** directive on food additives other than colors and sweeteners.
Annex I: list of food additives permitted for use in foodstuffs (excl. those listed in Annex II) following the "quantum satis" principle
Annex II: list of foodstuffs in which only a limited number of additives of Annex I may be used. These include cocoa and chocolate products, fruit juices and nectars, jam and jelly, dehydrated milk and cream, fruits and vegetables, rice, oils and fats, certain cheeses, minced meat, bread and pasta, wines and beer
Annex III: list of conditionally permitted preservatives and antioxidants
Annex IV: list of other permitted additives
Annex V: list of permitted carriers and carrier solvents
Annex VI: list of additives permitted in foods for infants and young children

These lists can be downloaded from our additives webpage.

An important difference from U.S. legislation is the use of flour bleaching agents: chlorine, bromates and peroxides are not allowed in the EU.

Specific information on authorized additives can be obtained from our office. Upon request, our office can also provide a multilingual list of all food additives.

Labeling requirements for additives and flavorings are laid down in directive 2001/13/EC (general labeling directive), regulation 50/2000/EC (GM additives) and directive 89/107/EEC. The addition of a new food additive to the EU positive list is a lengthy process. However, any

Member State can allow the domestic use of a new food additive on their territory for a two-year period. Companies are advised to submit an application to the Member State where they want to start using a new additive and simultaneously to the Commission. Procedures on obtaining the 2-year waiver differ from one Member State to another, and the time necessary to obtain approval also can vary significantly. The procedure for inclusion of an additive in the positive list requires that a dossier be sent to the European Food Safety Agency (EFSA) and to the Commission. EFSA reviews a substance and has to give a positive opinion before the Commission can propose the addition to the positive list.

Processing Aids

A list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their conditions of use has been established in Council Directive 88/344/EC.

Flavorings

In an initial step to harmonize the use of flavorings in the EU, the European Commission compiled a register of all flavoring substances authorized in the different EU member states. Substances that are subject to restrictive or prohibitive measures in certain member states have been marked. This register has been updated by Commission Decisions 2004/357/EC and 2005/389/EC.

SECTION 5. PESTICIDES AND CONTAMINANTS

http://useu.usmission.gov/agri/pesticides.html

The legislation on pesticides and contaminants is partially harmonized in the EU. Enforcement of both EU and remaining Member State rules is done at the Member State level.

Pesticides

EU pesticide legislation has not been fully harmonized yet and is under review. Community maximum residue levels (MRL's) take into account the work done by Codex Alimentarius and by the OECD but exceptions exist. An overview of all compounds for which harmonized MRL's have been developed are available from our website. The complete list of MRL/commodity combinations can be downloaded from the Commission's website at http://europa.eu.int/comm/food/plant/protection/pesticides/index_en.htm. Pesticide MRL's for processed or composite products are based on the MRL's for the raw agricultural ingredients. Harmonized sampling plans have been developed for the official control of residues (Commission Directive 2002/63/EC).

For the registration of a new pesticide in the EU, including the establishment of an MRL, an application needs to be prepared and reviewed by the relevant authorities and committees at Member State and EU level based on the rules set out in Directive 91/414. Pesticides that were already on the EU market when this directive was adopted have been undergoing a review. The currently ongoing legislative initiatives in the area of pesticides will have two main end results: the number of active substances will be drastically reduced and MRL's will become harmonized throughout the EU. Full harmonization of EU MRLs is not expected before 2007. MRL's for unapproved substances will all automatically revert to the default level of 0.01 mg/kg when the harmonization exercise is finalized. For pesticides that are not or no longer authorized at Community level or to accomodate Good Agricultural Practices (GAPs) which are specific for U.S. growing conditions, an import tolerance may be requested. Application dossiers are first submitted to a rapporteur Member State. Information on import tolerances can be obtained from http://www.pesticides.gov.uk/applicant_guide.asp?id=1239

Contaminants

http://useu.usmission.gov/agri/contaminants.html

Maximum Levels

EU wide harmonized maximum levels for contaminants are set in the Annex of Commission Regulation 466/2001. Over the years, this annex has been amended a number of times to include new maximum levels for nitrates, aflatoxin, ochratoxin A, heavy metals, dioxin, patulin, inorganic tin, fusarium and polycyclic aromatic hydrocarbons in foodstuffs (see Table 1).

Table 1: Amendments to Commission Regulation 466/2001	
Section 1: Nitrates	
Nitrate in lettuce and spinach and infant food	Commission Regulation 563/2002 Commission Regulation 1822/2005
Section 2: Mycotoxins	

Aflatoxins in nuts, dried fruit, cereals, maize, spices and milk	Commission Regulation 257/2002 Commission Regulation 472/2002 Commission Regulation 2174/2003 Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxin (European Commission Document)
Ochratoxin A in cereals, cereal products, dried vine fruit	Commission Regulation 472/2002 Commission Regulation 123/2005
Aflatoxin, ochratoxin A, nitrate in infant foods	Commission Regulation 683/2004 Commission Regulation 655/2004
Patulin in apple juice, apple juice ingredients	Commission Regulation 1425/2003 Commission Regulation 455/2004
Fusarium toxins in cereals and cereal products	Commission Regulation 856/2005
Section 3: Heavy metals	
Heavy metals lead, cadmium, mercury in fish	Commission Regulation 221/2002 Commission Regulation 78/2005
Section 4: 3-monochloropropane-1,2-diol (3-MCPD): no amendments	
Section 5: Dioxin and dioxin-like PCBs	
Dioxins in meat, fish, milk, eggs and oils & fats	Commission Regulation 2375/2001 (*) Commission Regulation 684/2004 (*) Commission Regulation 199/2006
Section 6: Tin	
Inorganic tin in canned foods & beverages, infant foods	Commission Regulation 242/2004
Section 7: PAH	
Polycyclic Aromatic Hydrocarbons (PAH) in oils and fats, infant foods, meat and fish	Commission Regulation 208/2005
(*) As of November 2006, levels established by Regulations 2375/2001 and 684/2004 will be replaced by the levels published in Regulation 199/2006. The last consolidated version of Regulation 466/2001 was published on Nov 29, 2005. This version does not include the most recent amendments on dioxin and dioxin-like PCBs (Commission Regulation 199/2006).	

Official Controls of Maximum Levels in Foodstuffs

The Directives in Table 2 concern the sampling methods and methods of analysis for the officialcontrols of the levels of the different contaminants. Annex I describes the methods of sampling;Annex II concerns the sample preparation and the performance criteria for the methods of analysis.

Table 2: Sampling & Analysis Methods for Official Controls	
Mycotoxins: Aflatoxins, Ochratoxin A, Patulin and Fusarium toxins	Commission Regulation 401/2006 (**)
Heavy metals & 3-MCPD	Commission Directive 2001/22/EC
Dioxins	Commission Directive 2002/69/EC
Tin	Commission Directive 2004/16/EC
PAH	Commission Directive 2005/10/EC

(**) Regulation 401/2006 replaces Directives 98/53/EC, 2002/26/EC, 2003/78/EC and 2005/38/EC as of March 29, 2006. It brings together the sampling methods and performance criteria for the methods of analysis to be used for the official controls of all mycotoxins in one single regulation.

Remark: Action levels for Dioxins in Foodstuffs
Action levels for dioxins and dioxin-like PCBs in foodstuffs are set by Commission Recommendation 2006/88/EC as part of a pro-active approach to reduce the presence of dioxins and dioxin-like PCBs in food and feed. The action levels for dioxins and furans are generally set at around 2/3 of the new maximum levels and an investigation into the cause of the contamination is required if the action levels are exceeded.

Residues in Animals and Animal Product

The monitoring of residues in animals and animal products is addressed separately in Council Directive 96/23/EC. This directive includes the monitoring of the above-mentioned pesticide residues but includes also the monitoring of residues of veterinary drugs and a wide range of other contaminants and undesired substances such as residues of growth promotants. The prohibition of the use of hormones in meat production is addressed in Council Directive 96/22/EEC.

SECTION 6. OTHER REGULATIONS AND REQUIREMENTS

A. Product Inspection and Registration

Member States are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further stages of marketing. Infringements of EU food and feed legislation are reported through the Rapid Alert System on Food and Feeds (RASFF). The rapid alert system is a network of Member State authorities managed by the European Commission. The weekly reports of the notifications under the rapid alert are available on the European Commission's website (http://europa.eu.int/comm/food/food/rapidalert/index_en.htm). The information published on the website is limited to the notifying country, the reason for notifying and the country of origin. Repeated non-compliance may lead to suspension of imports or special import conditions for products from the third country concerned, applicable on the entire EU territory.

Criteria for laboratories conducting food controls have been harmonized but it is the Member States' responsibility to designate laboratories that are allowed to perform analyses.

Specific detailed inspection requirements exist for animal products (Directive 97/78/EC). Products of animal origin must be presented at a Community border inspection post and submitted to an import control following prior notification of the shipment. Fresh fruits and vegetables are subject to phytosanitary controls and are checked for compliance with EU-harmonized marketing standards (see section 7.J).

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat and meat products, for which a waiver may be obtained from the listing requirement described below.

Inspection fees for non-animal origin products differ from one Member State to another. Measures in case of non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods (see section 7.B). The person/company introducing a novel food has to submit a request to the authorities in the Member States where the product will be marketed and a copy of this request has to be sent to the Commission's Health and Consumer Protection Directorate. Importers of organic products (see section 7.E) are required to notify the competent regulatory authority of the Member State of their activity. The introduction of foodstuffs with particular nutritional uses (see section 7.C) needs to be notified to the Member State where the food is sold. Exporters of vitamin-enriched foods or nutritional supplements are especially advised to check for the existence of specific Member State registration or notification requirements.

B. Certification and Documentation Requirements

http://useu.usmission.gov/agri/Certification_Guide.html

AGRIM Certificates

The EU requires import licenses (AGRIM certificates) for most agricultural products for which it provides market support, including grains, milk, meat, olive oil, most fruits and vegetables, wine and sugar. In order to obtain a license, an application form must be submitted and a

security fee must be paid to the issuing Member State. Licenses vary in validity with most expiring three months after the month of issuance.

Health and Quality Certificates

An overview of EU wide legally required certificates and voluntary certificates is provided in the EU Certification Guide (GAIN Report E36071). The vast majority of these certificates are health certificates, but some also refer to quality aspects such as organic certification. Certificates are grouped by product. Where possible, links are provided to the forms that U.S. agencies issue for health certification purposes. These forms are usually created in accordance with EU legislation, so we have also provided references to the relevant legislation. Please note that if there is no history of trade, U.S. government agencies may not have model certificates for all products.

These EU requirements pertain to all EU Member States. However, certain Member State specific requirements may exist where no EU wide provisions exist. An overview of this information is available from the FAS Member State certification reports:

Report Number	Title	Date Released
AU5017	Austria: Export Certificate Report	9/6/2005
BE5009	Belgium-Luxembourg: Certification Guide	9/2/2005
EZ5013	Czech Republic: Export Certificates Report	9/20/2005
DA5008	Denmark: Export Certificate Report	9/9/2005
FR5076	France: Certification Guide	11/3/2005
HU5012	Hungary: Export Certificate Report	9/9/2005
NL5025	Netherlands: Certification Guide	9/2/2005
PL5028	Poland: Certification Guide	1/26/2006
PO5019	Portugal: Export Certificate Report	8/22/2005
LO5011	Slovakia: Export Certificates Report	9/19/2005
SI5004	Slovenia: Export Certificate Report	1/26/2006
SP5028	Spain: Export Certificate Report	8/22/2005
SW5013	Sweden: Export Certificate Report	9/23/2005
UK5024	United Kingdom: Certification Guide	9/29/2005

Health Certificates for Plant Products
(http://useu.usmission.gov/agri/plantcertif.html)

Phytosanitary certificates are required under the EU's Plant Health Directive 2000/29/EC. Imports of fresh fruits and vegetables and unprocessed nuts must be accompanied by a U.S. Department of Agriculture phytosanitary certificate or PPQ577, issued by an official Animal and Plant Health Inspection Service (APHIS) inspector. The certificate is used to certify that the commodities have been inspected and that they comply with the importing country's phytosanitary regulations.
For more information see www.aphis.usda.gov/ppq/pim/exports/certificates&forms.htm.

Health Certificates for Animal Products
(http://useu.usmission.gov/agri/certification.html)

Animal products imported into the EU or transiting through the EU need to be accompanied by a veterinary certificate. EU harmonized health certificates are mandatory for meat, poultry, dairy, eggs, gelatin and seafood.

The European Community is well advanced in the process of harmonizing legislation on imports of animal products. This is a three-stage process that starts with the recognition of a country to export a certain animal product. The U.S. is recognized by the EU for all animal products. However, as a result of the EU's hormone ban and the rejection of chlorine as an anti-microbial treatment, U.S. exports of beef and poultry to the EU have been blocked. For more information see http://useu.usmission.gov/agri/ban.html and http://useu.usmission.gov/agri/pltryexp.html.

In a second stage, lists of EU approved establishments are drawn up in recognized countries. Various U.S. agencies, including FSIS, APHIS, AMS, and FDA are involved in the listing process. Contact information for the agencies issuing export certificates is available from our website or from the certificates report. Establishments are subject to occasional EU audits after listing. Exporters should be aware that getting a plant listed can take several months. Lists can be accessed through http://useu.usmission.gov/agri/estab.html. At present, the following food products must come from an EU-approved establishment: red meat, meat products, farmed & wild game meat, ratites, animal casings, milk & milk products, fish & fishery products and gelatin.

An importer must give at least 24 hours notice of intent to import animal products to the competent Member State authority and to the Border Inspection Post (BIPs) at the port or airport of entry. The list of EU Border Inspection Posts can be found on our website at http://useu.usmission.gov/agri/borderposts.html.

Health Certificates for Processed Foods
(http://useu.usmission.gov/agri/foodcertif.html)

All animal products imported into the EU need animal or public health certification. For processed foods containing animal product, the situation is more complicated because there is no legislation specifying the percentage of dairy, egg, red meat or poultry meat that a foodstuff must contain to necessitate certification. As such, the import rules in different EU Member States may slightly differ and it is best to check the documentation requirements with the importer. In principle, products containing any amount of red meat or poultry meat must be certified. Certification of products containing egg products or dairy products depends on the composition of the product. In the past, the Commission has advised that as a rough guideline, foodstuffs containing more than 50 percent egg/dairy products should

need the corresponding certificate. Again, implementation of this requirement is likely to be different in the Member states.

Although there are no harmonized EU certificates for processed foods such as canned vegetables, soup broths, etc., EU member states often require that shipments be accompanied by a certificate signed by U.S. officials. Exporters should check with their importer or with the Office of Agricultural Affairs in the importing Member State which documentation is required.

An overview of legally required certificates in the EU and references to the U.S. authority issuing these certificates is available on our website at http://useu.usmission.gov/agri/Certification_Guide.html.

SECTION 7. OTHER SPECIFIC STANDARDS

A. Genetically Modified Foods (GMOs)

http://useu.usmission.gov/agri/GMOs.html

Labeling regulations for GM food products are established by Regulation 1829/2003 (articles 12-13). These rules apply to products that have undergone varying degrees of processing. The regulation does not require labeling of food products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling.

The traceability rules require all business operators to transmit and retain information on GM products in order to identify both the supplier and the buyer of the GM product.

All food products containing or consisting of GMOs, produced from GMOs or containing ingredients produced from GMOs must be labeled even if they no longer contain detectable traces of GMOs. The allowable adventitious presence level for EU-approved varieties of GMOs is set at 0.9 percent. Above this level all products must be labeled. For GM varieties that received a positive EU risk assessment but are not yet formally approved, the adventitious presence level is set at 0.5 percent. A list of these varieties is available at http://ec.europa.eu/food/food/biotechnology/gmfood/events_en.pdf.

The wording to be used on GM food labels is as follows:

- Where the food consists of more than one ingredient, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must follow in brackets immediately after the ingredient concerned. A compound ingredient with a GM component should be labeled “contains [name of ingredient] produced from genetically modified [name of organism]”.

- Where the ingredient is designated by the name of a category (e.g. vegetable oil), the words “contains genetically modified [name of organism]” or “contains [name of ingredient] produced from genetically modified [name of organism]” must be used.

- Where there is no list on ingredients, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must appear clearly in the labeling.

The designations may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients or, where there is no list of ingredients, clearly on the labeling.

For more information see the Annual Agricultural Biotechnology Report (GAIN report E36080).

B. Novel Foods

(http://useu.usmission.gov/agri/novelfood.html)

The Novel Food Regulation 258/97 lays down detailed rules for the authorization of novel foods and novel food ingredients, including foods derived from or containing or consisting of GMOs. It defines novel foods as foods and food ingredients that were not used to a significant degree in the EU before May 15, 1997. The new regulations on GM food provide for a separate regime to deal with the authorization and traceability of novel foods and novel food ingredients that consist of or contain or are derived from GMOs. Pre-market approval of

non-GM novel foods will continue under European Parliament and Council Regulation 258/97. Non-GM categories of novel foods consist of food and food ingredients:

- with a new intentionally modified primary molecular structure, or
- consisting of, or isolated from, micro-organisms, fungi or algae, or
- consisting of, or isolated from plants or animals, except for foods and food ingredients obtained by traditional propagating or breeding practices with a history of safe use, or
- to which a production process not currently used has been applied, where that process changes the composition or structure of the food or food ingredient significantly

The full list of novel food applications and authorizations/rejections/withdrawals is available from http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf.

C. Dietetic or Special Use Foods
(http://useu.usmission.gov/agri/partnutr.html)

Council Directive 89/398/EEC is a framework directive laying down rules for foodstuffs intended for particular nutritional uses. These are foodstuffs, which due to their special composition or manufacturing process, can clearly be distinguished from foodstuffs for normal consumption. Commission Directive 2001/15/EC lists the chemical substances in each category of nutritional substances (vitamins, minerals and amino acids) that may be added for specific nutritional purposes in foodstuffs for particular nutritional uses.

Provisions including compositional and hygiene requirements, provisions regarding the quality of raw materials, a list of additives/substances, specific labeling requirements, sampling procedures and analysis methods have been laid down in specific directives for four product categories:

- Commission Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children.
- Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction.
- Commission Directive 91/321/EC on infant formula and follow-on formula.
- Commission Directive 1999/21/EC on dietary foods for special medical purposes.

To take advantage of technological developments, the Commission may authorize the marketing of products, which do not comply with the requirements of the specific directives for a two-year period.

Specific directives on foods and beverages for sports people or on foods intended for diabetics are still subject to Member State legislation. The introduction of foodstuffs intended for particular nutritional uses for which no specific rules are set must be notified to the Member State where the food is sold.

D. Wine, Beer and Other Alcoholic Beverages
(http://useu.usmission.gov/agri/wine.html)

Wine labeling rules are laid down in Annex VII to Council Regulation 1493/1999, the EU's basic wine regulation. Commission Regulation 753/2002 lays down rules for applying the provisions contained in regulation 1493/1999, which relate to the description, designation, presentation and protection of certain wine sector products.

On March 10, 2006, the U.S. and the EU and the U.S. signed the "Agreement between the United States and the European Community on Trade in Wine". This Agreement is the first

phase and addresses a number of issues, such as labeling and certification. Other important issues such as geographical indications will be addressed in a second phase of the negotiations (expected to start mid 2006). The Agreement covers wine with an actual alcohol content of not less than 7% and not more than 22%. All U.S. wine imports must be accompanied by a certification document using the format specified in Annex III(a) to the Agreement. The Agreement's "Protocol on Wine Labeling" sets conditions for the use of optional particulars on wine labels.

GAIN report E36067 gives an overview of the mandatory information required on wine labels and lists the conditions for supplementing the mandatory information with optional information. Information on the US-EU Wine Agreement can also be obtained from the U.S. Dept. of the Treasury - Alcohol and Tobacco Tax and Trade Bureau (http://www.ttb.gov/international_trade/us_ec_wine_agreement.htm).

Council Regulation 1576/89, as amended, lays down the general rules on the definition, description and presentation of spirit drinks. There is no Community legislation for beer, although some member states have adopted national provisions to make the list of ingredients compulsory.

Alcoholic beverages containing sulphur dioxide and sulphites at concentrations of more than 10 mg/liter must be labeled "contains sulphites" or "contains sulphur dioxide". Replacing the word "sulphites" by "SO_2" or the E-number (E220) is not allowed. The list of authorized languages for allergen labeling can be consulted in GAIN report E36066.

E. Organic Foods
(http://useu.usmission.gov/agri/organic.html)

Council Regulation 2092/91, as amended, on organic products covers the following requirements and definitions: production and processing methods, labeling and marketing, inspection and imports from third countries. It was supplemented by Regulation 1804/99 to include livestock production. The term "organic" on the label may only be used for product conforming these regulations.

While organic standards have been set at the EU level, implementation and enforcement of the regulation is the responsibility of the individual member states. This member state responsibility also extends to imports of organic products. In order to import U.S. organic products, EU importers must work through their designated member state authority to obtain an import authorization. These authorizations are granted on a case-by-case basis, subject to the member state's review of two main elements: the organic standards and inspection measures applied by the certifier of the product and the certifier's compliance with EN 45011 or ISO Guide 65.

The importer must demonstrate that the product was produced according to standards equivalent to the EU standards. In addition, the importer must provide evidence that the certifier of the product has been accredited to EN 45011/ISO 65 by an authority recognized by the member state. Individual member states may have different criteria for judging compliance with these requirements. In the U.S., USDA' Agriculture Marketing Service (AMS) has been designated as the competent authority to accredit U.S. organic certifiers for compliance with ISO 65. To date, Austria, Netherlands, Denmark, Spain, Sweden, United Kingdom and certain German states have officially recognized AMS' ISO 65 accreditation.

Commission Regulation 1788/2001 lays down detailed rules for a certificate of inspection for imports from third countries. Certifiers of U.S. organic products must use the EU certificate format for products to be exported to the EU. An original certificate must accompany the

good and is verified at the border by the member state authorities. Goods are not released until the authorities have verified that a valid import authorization has been granted for the consignment. Member states have several options for implementing the regulation, which means that procedures may differ from member state to member state.

F. Vertical Legislation (Breakfast Directives)
(http://useu.usmission.gov/agri/vertic.html)

Vertical legislation on the manufacture and marketing of specific products has been developed for sugars, cocoa and chocolate products, honey, fruit juices and similar products, preserved milk, coffee extracts and chicory extracts and fruit jams and similar products.

G. Animal Products

Beef Labeling (http://useu.usmission.gov/agri/label)

A compulsory beef labeling scheme has been in place since September 2000. Full implementation of the beef labeling scheme went into effect on January 1, 2002. (Regulations 1760/2000 and 1825/2000). Under this scheme, labels for all bovine meat must indicate the following information:

"Born in: name of third country"
"Reared in: name of third country or third countries"
For beef derived from animals born, raised and slaughtered in the same third country, the above indications may be combined as "Origin: name of third country"
A reference number ensuring the link between the meat and the animal or animals
"Slaughtered in: third country / approval number of slaughterhouse"
"Cutting in: third country / approval number of cutting plant"
A traceability code linking the meat to the animal or a group of animals representing the production of maximum one day

Egg Labeling (http://useu.usmission.gov/agri/label.html)

The mandatory marking of grade A eggs (fresh eggs for human consumption) by a code designating the producer and farming method entered into force on January 1, 2004, as part of an amendment to Council Regulation 1907/90 establishing marketing standards for eggs. Each egg produced in the EU has to be stamped individually with one of the following codes indicating the farming method: O = organic, 1 = free range, 2 = barn, 3 = cage. For eggs imported from the U.S., the new rules are not totally clear yet. The European Commission must first evaluate the U.S. labeling rules in force to determine whether they are equivalent to the EU's technical rules and standards. Pending the outcome of this evaluation, imported grade A eggs may be stamped individually with either a code corresponding to the mentioned methods of production or with a code identifying the unspecified nature of the farming method.

Other

- Council Regulation 1906/90 of 26 June 1990 on certain marketing standards for poultry
- Council Regulation 1898/87 limits the use of the word "milk" or other dairy products to actual dairy products
- Council Regulation 2991/94 establishes standards for spreadable fats

- Council Regulation 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products

Product briefs on seafood and pet food can be found on our website at http://useu.usmission.gov/agri/seafood2.html and http://useu.usmission.gov/agri/petfood.html.

H. Frozen Foodstuffs
(http://useu.usmission.gov/agri/frozen.html)

Council Directive 89/108/EEC sets rules for quick-frozen foodstuffs and for their packaging and labeling. Quick-frozen foodstuffs sold to the final consumer should carry the following additional labeling indications: the product name with the indication “quick-frozen”, the date of minimum shelf life, the period during which the purchaser may store the product, the storage temperature and/or type of storage equipment required, batch identification and a clear indication of the type “do not re-freeze after defrosting”.

I. Irradiated Foodstuffs
(hhtp://useu.usmission.gov/agri/irradiation.html)

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU- wide approval.

Framework Directive 1999/2/EC outlines the marketing, labeling, import and control procedures and technical aspects of food irradiation. Irradiated foods must be labeled "irradiated" or "treated with ionizing radiation".

Implementing Directive 1999/3/EC establishes a Community list of foods and food ingredients authorized for irradiation treatment. The list contains only one food category: "dried aromatic herbs, spices and vegetable seasonings". Until the positive list is expanded, the national authorizations listed on our website continue to apply.

J. Fruits and Vegetables
(http://useu.usmission.gov/agri/Fruit-Veg.html)

Fresh fruits, vegetables and nuts are subject to phytosanitary controls (see section 6.B) and are checked for compliance with EU marketing standards for quality and labeling. A conformity certificate or a certificate of industrial use, to be obtained by the importer at the point of entry, is required for all shipments of fresh produce. Marketing standards for fruits and vegetables are available on our website. Standards exist for apples and pears, apricots, artichokes, asparagus, aubergines (eggplant), avocados, beans, Brussels sprouts, cabbage, carrots, cauliflowers, celery, cherries, citrus fruit, courgettes (zucchini), cucumbers, garlic, kiwis, leeks, lettuce, curly and escarole chicory, melons, onions, peaches and nectarines, peas for shelling, plums, spinach, strawberries, sweet peppers, table grapes, tomatoes, watermelons, witloof chicory, miniature produce, mixes of fruit and vegetables, walnuts and hazelnuts.

K. Seafood
(http://useu.usmission.gov/agri/seafood2.html)

Fishery and aquaculture products offered for retail sale in the EU must be properly labeled providing the following information:

- Commercial name of the species (each member state has established a list of commercial designations).
- Product method: “caught in…”, “caught in freshwater”, “farmed” or “cultivated”.
- Catch area: for products caught at sea, a reference to one of the areas listed in the annex. For products caught in freshwater, a reference to the country of origin; for farmed products, a reference to the country in which the product undergoes the final development stage. Operators may indicate a more precise catch area. To improve the traceability and control at all marketing stages - from the ship to the shop - the information concerning the commercial designation, the production method and the catch area for all fishery and aquaculture products must be provided either on the label, on the packaging or by means of a commercial document accompanying the goods (e.g. the invoice).

SECTION 8. COPYRIGHT AND/OR TRADEMARK LAWS

Trademarks

Community trademark policy was created by Council Regulation 40/94 and implemented by Commission Regulation 2868/95. This regulation creates a single, unitary registration system covering the whole Community territory.

In practice, a Community trademark must meet two conditions: it must be a sign which can be represented in graphic form, and it must make it possible to distinguish goods and services from those of another company. It is valid for a period of 10 years. Applications for registering Community trademarks under these regulations may be filed with the Alicante, Spain, based Office of Harmonization for the Internal Market, subject to the fees set out in Commission Regulation 2869/95, or at a national industrial property office in a Member State of the European Union.

On completion of the registration procedure, the trademark is registered in the Register of Community trademarks.

The Community Trademark did not replace the existing trademark laws of the member states, for which a need will continue to exist, but co-exists alongside national trademarks. Council Directive 89/104/EEC approximates national trademark rules as regards what can and cannot be registered, the exclusivity of rights and conditions under which trademark rights can be forfeited.

Protected Geographical Indications

Geographical indications (GIs) are “indications which identify a good where a given quality, reputation or characteristic of the good is essentially attributable to its geographic origin”. Council Regulation 510/2006 on the protection of geographical indications/designations of origin for listed European agricultural products and foodstuffs repeals Regulation 2081/92 to bring its rules in line with a WTO ruling. The new regulation allows third country operators to submit registration applications directly to the Commission rather than through their governments and deletes reciprocity requirements. It also allows third countries to object directly to new registrations. Guidelines for the registration of GIs by third country producers have been published on the Commission’s website at http://ec.europa.eu/agriculture/foodqual/protec/thirdcountries/proced_en.pdf.
The complete list of registered product names that receive protection in the EU can be found at http://ec.europa.eu/agriculture/qual/en/1bbaa_en.htm.

SECTION 9. IMPORT PROCEDURES

Council Regulation 2913/92 establishes the Community Customs Code. The Code lists all the customs procedures applicable to the trade in goods with third countries. Import duties are determined by the tariff classification of goods and by the customs value. With the implementation of the Code, the member states of the European Union form a customs union which means that all the member states apply the same tariff on goods imported from outside the EU. Once an imported good is cleared in one member state, it can move freely throughout the EU.

The EU uses the Combined Nomenclature (CN) for the customs classification of goods. The CN eight digit code numbers are based on the Harmonized System (HS) nomenclature: the first six digits refer to the HS headings, the two following digits represent the CN subheadings. The EU's on-line customs database can be consulted to look up commodity codes and relevant import duties (http://ec.europa.eu/taxation_customs/dds/en/tarhome.htm). It is also possible to obtain Binding Tariff Information (BTI) from a member state's customs authority to get the proper product classification. Through this system, traders know in advance the tariff classification of the goods they intend to import. BTI is legally binding in all the member states. A list of customs authorities can be found on the Internet at http://ec.europa.eu/taxation_customs/common/links/customs/index_en.htm. The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading.

Goods are only released after payment of the import duty and other taxes that may be due. Duties payable on goods imported into the EU may include:

- import duty (expressed as ad valorem tariffs or specific tariffs per unit weight/volume/number of pieces)
- additional duties on flour and sugar (processed products)
- entry price (fruit and vegetables)
- environmental taxes - not harmonized
- inspection fees - not harmonized
- Value Added Tax (VAT) - not harmonized
- excise duties (alcohol and tobacco) - not harmonized

A list of VAT rates applicable in the different member states can be found on the Internet at http://ec.europa.eu/taxation_customs/taxation/vat/consumers/vat_rates/index_en.htm.

A list of excise duties applicable on alcoholic beverages and tobacco can be found at http://ec.europa.eu/taxation_customs/taxation/excise_duties/alcoholic_beverages/rates/index_en.htm and http://ec.europa.eu/comm/taxation_customs/taxation/excise_duties/tobacco_products/rates/index_en.htm respectively.

Other customs procedures described in detail in the Code include entry into free zones, situations where no import duty is payable: e.g. the inward processing regime, under which goods can be imported for processing but the finished product must be exported from the Community market. The Code also provides for a two-stage right of appeal lodged in the Member State where a decision has been taken or applied for: in the first instance to the customs authority, then to the national courts.

APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS

Commission of the European Communities
Rue de la Loi 200
1049 Brussels
Belgium
Tel: (32-2) 299 11 11

Office for Harmonization in the Internal Market
Avenida de Aguilera, 20
03080 Alicante
Spain
Tel. (34-96) 513 92 43
Fax. (34-96) 513 91 73

European Union - Delegation of the European Commission to the United States
2300 M Street
NW, Washington, DC 20037
Tel: (202) 862-9500
Fax: (202) 429-1766

United States Mission to the European Union
Office of Agricultural Affairs
Mailing address:
27 Boulevard du Regent
1000 Brussels
Belgium
Tel: (32-2)508-2760
Fax: (32) (2) 511-0918
e-mail: AgUSEUBrussels@usda.gov

Other FAS Offices in the European Union http:/useu.usmission.gov/agri/FAS-inEU-25.html

USDA/FDA contacts for certification of Animal Products
http://useu.usmission.gov/agri/certification.html

APPENDIX II. HOW TO OBTAIN LEGISLATION
http://useu.usmission.gov/agri/legis.html

The Official Journal (http://europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en)

The Official Journal is the EU equivalent to the U.S. Government's "Federal Register". The L (Legislation) and C (Information and Notices) series of the Official Journal are published daily in all the official languages of the EU.

Legislation in force (http://eur-lex.europa.eu/en/legis/index.htm)

The texts are arranged under twenty main chapter headings. Legislation relating to agriculture, biotechnology, organic farming, foodstuffs, etc. can be found under heading 03 "Agriculture" and heading 15 "Environment, Consumers and Health Protection". On this site you can find the initial legislation and all the amendments as published in the Official Journal. The Directory also gives access to **consolidated texts**, which have no legal value but which integrate a basic instrument of Community legislation with its subsequent amendments and corrections in a single text.

APPENDIX III. EU INITIATIVES

This report gives an overview of EU food laws currently in force. However, below follows a list of EU proposals / initiatives that may possibly affect U.S. food exports to the EU:

- Acrylamide
- Additives
- Animal welfare labeling
- Enzymes
- Food contact materials
- Food supplements
- Fortified foods
- Functional foods
- Infant formulae
- Novel foods
- Nutrition, functional and health claims
- Nutrition labeling
- Organic food
- Pack sizes
- Pesticides
- Review of labeling rules
- Spirit drinks
- Sweeteners

Please check our website (http://useu.usmission.gov/agri/usda.html) for updates on legislative developments. You can also subscribe to our bi-weekly e-newsletter "What's new on the USEU Agric Website" by sending an e-mail to Hilde.Brans@usda.gov.

USEU Reports on EU Proposals:

Report Number	Title	Date Released
E36087	EP passes new EU rules on fortified foods	5/24/2006
E36086	EP passes new EU rules on nutrition & health claims	5/24/2006
E36045	EU Food Labeling Review	3/14/2006
E36040	EU Proposal: Definition & Labeling of Spirit Drinks	3/7/2006
E35221	Eco-Labeling Schemes for Fisheries Products	11/18/2005
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